Analyses of obeticholic acid treatment retention in UK patients based on medicine delivery data

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INTRODUCTION

Between 30-40% of patients with primary biliary cholangitis (PBC) inadequately respond to Ursodeoxycholic acid (UDCA) and are candidates for second-line therapy.

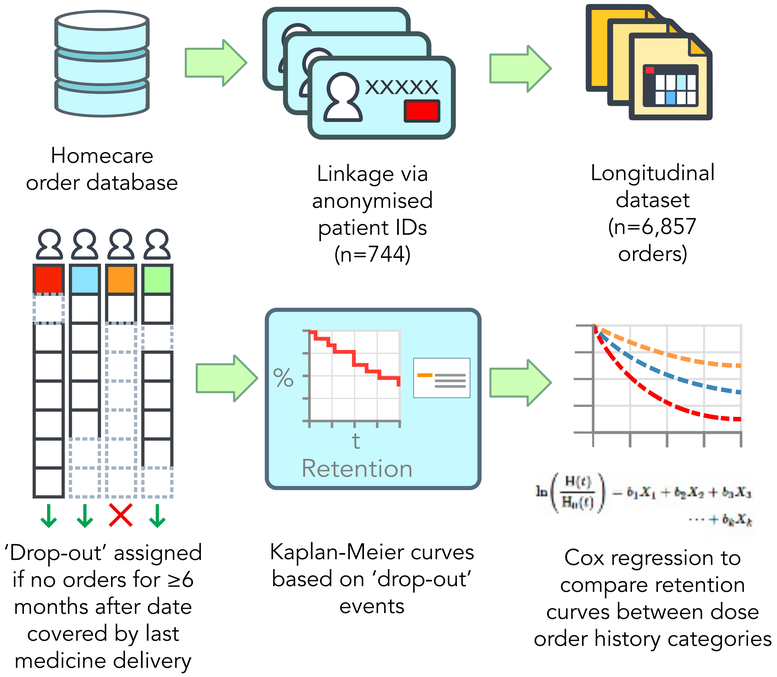
Obeticholic acid (OCA) is the only licensed second-line treatment in the UK, however, compliance, treatment adherence and rates of drug discontinuation have not been quantified at scale.

The objective of this analysis was to study drug discontinuation rates for PBC patients receiving OCA in the UK, based on real-world order data.

METHODS

Our analysis examined orders for OCA delivered to PBC patients through the manufacturer-sponsored Homecare Medicines Service. The data analysis is summarized in Figure 1.

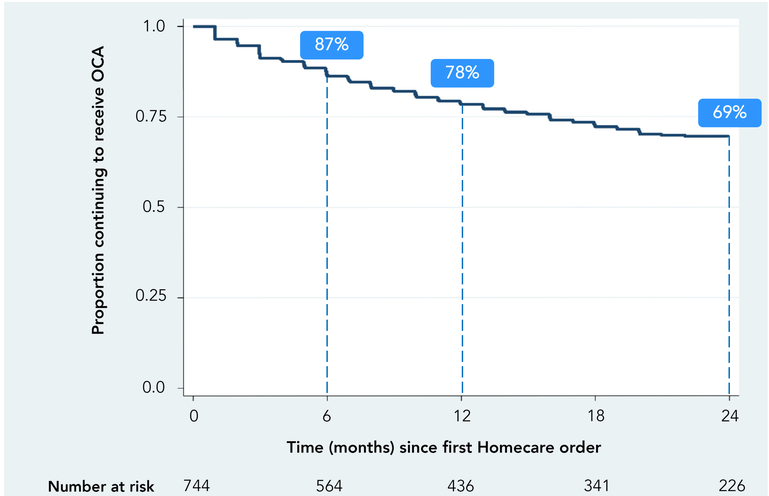
Figure 1. Analysis flow



RESULTS

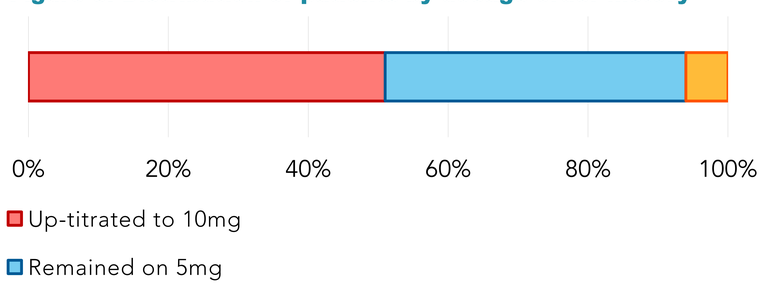
6,857 orders in 744 patients yielded 1,138 person-years of ordering data with 204 drop-out events. The estimated rates of OCA retention from time of first order are shown in see Figure 2.

Figure 2. Proportion of patients continuing to receive OCA by time since first order



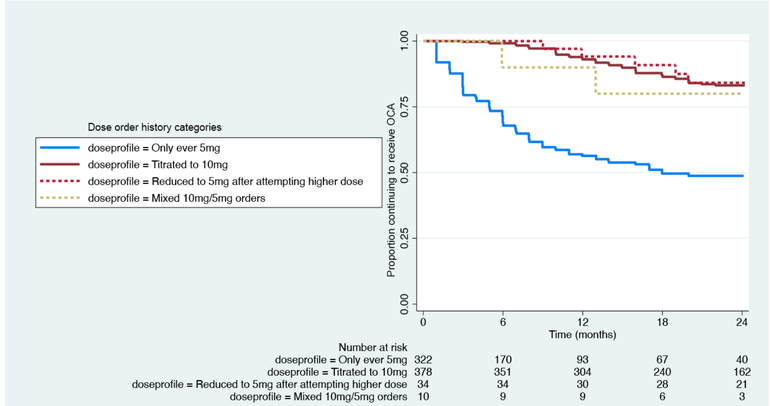
Only 51% of patients had order histories indicating successful titration to 10mg OCA daily doses: the distribution is shown in Figure 3.

Figure 3. Distribution of patients by dosage order history



We observed marked separation between some dose order groups in terms of drop-out (See Figure 4). The 5mg only group was most likely to drop out (69%, 56%, and 49% remaining on treatment at 6, 12 and 24 months respectively). By contrast, those who received 10mg dosing (at any point) remained on OCA at a rate of 99%, 93%, and 82% at 6, 12 and 24 months respectively. The difference in retention was statistically significant (hazard ratio of 10mg vs 5mg only dosing = 0.22, 95% CI 0.17, 0.30, p<0.001). This hazard ratio remained statistically significant in a restricted analysis of those receiving OCA for ≥6 months.

Figure 4. Proportion of patients continuing to receive OCA orders by time since first Homecare order, separated by dose order history categories



CONCLUSION

Our findings suggest an association between dose order history and treatment retention. This, along with indications in the order dataset that retention may vary between UK centres, prompts further study into optimal systems of management and support for patients on OCA. Conclusions about drop-out should be made with caution, since the analyses only consider product orders, disconnected from patient clinical characteristics and prescription data. A future study of treatment retention on OCA could aim to address these factors by using real-world, patient-level data.

DISCLOSURES

The analysis and poster preparation were carried out by Intercept Pharmaceuticals, Ltd (UK). C Gibbons, S Srinivasan, J Bodhani, J Li, L Chen, are employees of Intercept Pharmaceuticals.

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